



Wyeth Pharmaceuticals
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March 22, 2004

Mr. John Becher
Centers for Disease Control/Drug Service, D-09
1600 Clifton Road
Atlanta, GA 30333

Re: STN 101106 - Smallpox Vaccine, Dryvax[®]

Dear Mr. Becher:

Please note that Wyeth received approval on March 19, 2004 for BLA Supplement STN 101106/5045 to extend dating of Lots 4020072, 4020074 and 4020075 of Smallpox Vaccine, Dryvax[®] from 24 to 30 months as indicated:

<u>Packaged Lot Number</u>	<u>Current Expiration Date</u>	<u>New Expiration Date</u>
4020072	March 2004	September 2004
4020074	April 2004	October 2004
4020075	May 2004	November 2004

Additional testing in accordance with the protocol filed to our license will be conducted and a CBE supplement will be submitted to extend the expiration dating beyond 30 months, if appropriate.

Please note that the storage period of the vaccine after reconstitution with diluent continues to be 90 days.

Sincerely yours,

Dennis J. Foley, Ph.D.

DJF:jm

cc: J. Goodman, CBER
J. Grabenstein, U.S.AMC
K. Midthun, CBER
D. Staten, CBER
D. Yeskey, HHS